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DEPARTMENT OF HEALTH



HEALTH REGULATION AND LICENSING ADMINISTRATION

Adverse Events in the District of Columbia

Annual Report December 2008

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Executive Summary

Improving Healthcare Delivery in the District of Columbia

In December 2006, the District of Columbia passed the Medical Malpractice Amendment Act of 2006. Effective July 1, 2007, the Act mandates that any licensed healthcare provider or medical facility must report adverse events, which include 28 “never events” as defined by the National Quality Forum (NQF), plus one type of hospital-acquired (HAI) infection, to the Department of Health (the Department) biannually. The Department is charged with analyzing these reports, identifying patterns or trends, recommending methods to reduce systematic adverse events, providing technical assistance to healthcare providers and medical facilities, and disseminating information and advice on best practices.

The Act requires the Department to publish an annual report “that includes summary data of the number and types of adverse events of the prior calendar year by type of healthcare providers and medical facility, rates of change, and other analyses and communicating recommendations to improve healthcare delivery in the District of Columbia.”

This annual report includes an analysis of the adverse event reports received pursuant to the Act for the reporting period July 1, 2007, through June 30, 2008. The numbers and types of adverse events reported are presented in Table 1. The number and types of reports submitted by different facilities/providers is presented in Tables 4 and 5. Recommendations based on best practices relevant to adverse events that have occurred during this reporting period are provided in the section “Guidance and Recommendations” in the ongoing effort to improve healthcare delivery in the District of Columbia.

Data Collection—Patterns and Trends in Adverse Event Reports

Collecting and analyzing reports of adverse events is a vital component in the District of Columbia’s goal to improve healthcare delivery. Reports are submitted to the Department in hardcopy or by facsimile utilizing a standard Adverse Event Report Form. The Act requires that adverse events be reported with patient information that is de-identified and anonymous.

During the reporting period July 2007 through June 2008, the District’s healthcare providers and medical facilities submitted a total of 529 adverse event reports. Two of these reports were duplicates, and three reports, submitted by a health clinic and a nursing facility, indicate that no reportable events occurred at the facility; these reports are not included in the analysis of event reports. Fourteen (3%) of the reports involved a patient death. Hospitals submitted 384 (73%) of the reports; 138 (26%) were submitted by long-term acute care hospitals, and the remaining two reports were submitted by a nursing home or a practitioner’s office.

The Department has adopted NQF’s list of “Serious Reportable Events” (often referred to as “never events”) as a taxonomy for reportable events. In addition to the 28 never events, the Department collects one type of HAI: central-catheter-associated laboratory-confirmed primary bloodstream infection (i.e., central-line-associated bloodstream infection [CLABSI]). The most commonly reported event types were CLABSIs, pressure ulcers, and retained foreign bodies, representing 92% of reports submitted. Six percent of the reports did not specify the event type.

Highlights of the data submitted to the Department for the reporting period July 2007 to June 2008 include the following:

- A total of 529 adverse event reports were received.
- Fourteen reports (3%) involved a patient death.
- The majority of reports, 382 (73%), were submitted by hospitals.

The adverse event reports submitted by healthcare providers and medical facilities in the inaugural year of the District's reporting program are a good start. Clarification of the definitions of reportable adverse events and standardization of reporting by healthcare providers and facilities are the next steps towards improvement. Initially, the District can expect an increase in reported adverse events as a result of these efforts. However, an initial increase in reported adverse events will reflect the commitment of healthcare providers and medical facilities to the growth of a robust source of guidance and best practices. The longer-term goal is a decrease in the number of adverse events that accurately reflects improvement in the safety of healthcare delivery in the District.

Guidance for Healthcare Providers and Medical Facilities

One of the chief goals of any reporting program is to prevent the occurrence of similar adverse events in the future. By analyzing the causes of adverse events, we hope to find and repair the weaknesses in clinical processes in order to prevent the same events from happening to other patients or residents.

At the facility or provider level, the analysis of an individual adverse event can uncover the root cause and contributing factors underlying the adverse event and provide the basis for development of strategies to prevent recurrence. However, at this level of analysis, it may be difficult to determine trends in the data related to the type or volume of adverse events experienced by a provider or facility. When a particular type of adverse event occurs rarely, a facility may view it as a random occurrence, and the potential to implement systems and processes for prevention may be lost.

Aggregating adverse event data gathered from facilities and providers throughout the District is a powerful tool in identifying trends in events undermining safe and effective healthcare. Analysis of the information received through the District's reporting program will serve as the basis for meaningful insights, lessons learned, and best practices that can improve patient safety.

Introduction

Adverse Event Reporting and Patient Safety

Medical errors and adverse events are a significant killer in the United States, and most are preventable. According to the Institute of Medicine (IOM), more than 1 million preventable adverse events occur each year in the United States, of which 44,000 to 98,000 are fatal.¹ Although the accuracy of these numbers has been questioned, there is general consensus throughout the healthcare community that safety is a significant problem in virtually all care settings and that the healthcare system frequently puts patients at unnecessary risk.

Since IOM published *To Err is Human*, both the healthcare community and the general public have become considerably more aware of and sensitive to the issues surrounding patient safety. One of the principal recommendations of the IOM report was to create a mandatory reporting system for the most serious events. In response, several healthcare error reporting systems have been launched by public and private entities. For example, the Joint Commission implemented its Sentinel Event Policy (SEP) following the publication of the IOM report. SEP instructs organizations to identify sentinel events, complete a thorough root-cause analysis of those events, implement strategies to reduce their prevalence, track the effectiveness of those strategies, and share lessons learned.²

Reporting systems are an important mechanism for generating knowledge about errors and their underlying causes. They help healthcare providers learn from experience, share lessons learned, and monitor their progress over time. When reports are shared beyond the four walls of a healthcare facility to an external party that aggregates and analyzes the results, there is a remarkable opportunity to disseminate lessons more broadly. The National Academy for State Health Policy and others have identified many ways in which public reporting systems can stimulate improvements in the safety and quality of patient care.³

For example:

- Safety alerts about new hazards can be generated from just a few or even one significant report.
- Safety alerts about hazards can be generated from analysis across many reports that reveals patterns and trends.
- Best practices can be gleaned from data-driven analyses, particularly in trying to identify the performance factors that help some facilities prevent or recover from certain types of errors while other facilities do not.

The importance of collecting of data systematically was recognized at the federal level, leading to the establishment of the National Quality Forum (NQF), a voluntary consensus standards-setting organization. NQF has developed a list of serious reportable events in healthcare that should never occur, commonly referred to as “never events.” Not intended to capture all adverse events, the list focuses on those that are: (1) clearly identifiable and measurable; (2) of a nature such that the risk of

¹ Institute of Medicine Committee on Quality of Health Care in America. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Washington (DC): National Academy Press; 1999 Nov 1:223 p.

² Sentinel Events. In: Joint Commission. *Comprehensive Accreditation Manual for Hospitals*. Oakbrook Terrace (IL): Joint Commission Resources; 2006.

occurrence is significantly influenced by the policies and procedures of the healthcare facility; and (3) of concern to both healthcare providers and the public.³

In addition, to be considered a serious reportable event, an event must be unambiguous, usually preventable, serious, and one or more of the following:

- Adverse
- Indicative of a problem in a healthcare facility's safety systems
- Important for public credibility or public accountability

Requiring that an event be "usually preventable" acknowledges that some of these events are not always avoidable, given the complexity of the healthcare industry. The presence of an event on the list, therefore, is not an *a priori* judgment of either a systems failure or lack of due care. Of note, the frequency with which an event occurs was considered but was not accepted as a criterion for inclusion of events on the list.

The ability to derive and disseminate good lessons from bad events is a hallmark of an effective reporting system. The primary goals are to prevent harm and enhance public trust. Through the establishment of an adverse event reporting program that encompasses standardized reporting requirements, the District has taken an important step in achieving this goal.

³ National Quality Forum (NQF). *Serious reportable events in healthcare 2006 update: a consensus report*. Washington (DC): NQF; 2007.

Data Collection and Analysis

The Reporting Program

Effective July 2007, the District has mandated the reporting of adverse events, defined as “an event, occurrence, or situation involving the medical care of a patient by a health care provider that results in death or an unanticipated injury to the patient.” The law requires reporting by a broad range of healthcare providers and medical facilities. Adverse events that must be reported include the 28 NQF Serious Reportable Events and one healthcare-associated infection (HAI): central-line-associated bloodstream infection (CLABSI). A standardized Adverse Event Reporting Form is available to medical facilities and healthcare providers for this purpose. Reports must be submitted via mail or facsimile to the appointed system administrator in the Department of Health on January 1 and July 1 of each calendar year. A monetary penalty is imposed for failure to report. The Department collects and analyzes the reports, providing an annual report including summary data and recommendations. The Act contains well-defined confidentiality provisions related to reporters and information provided to the system administrator.

Reports by Event Type

In the inaugural reporting period, which covered events occurring between July 1, 2007, and June 30, 2008, District medical facilities and healthcare providers submitted 524 reports to the Department. The most frequently reported types of events were CLABSIs, pressure ulcers, and retained foreign bodies, representing 92% of reports submitted. Thirty-two (6%) of the reports did not specify the event type. Table 1 summarizes the reports submitted by event type.

Table 1. Number and Percentage of Reports by Event Type

Event Category	Event Type	No.	%
Surgical Events	1A - Surgery performed on the wrong body part	3	1
	1B - Surgery performed on the wrong patient	1	<1
	1C - Wrong surgical procedure performed on a patient	1	<1
	1D - Unintended retention of a foreign object in a patient after surgery or other procedure	10	2
	1E - Intraoperative or immediately postoperative death in an ASA (American Society of Anesthesiologists) Class I patient	0	0
Product or Device Events	2A - Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	0	0
	2B - Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	1	<1
	2C - Patient death or serious disability associated with intravascular air embolism that occurs while the patient is being cared for in a healthcare facility	0	0
Patient Protection Events	3A - Infant discharged to the wrong person	0	0
	3B - Patient death or serious disability associated with patient leaving the facility without permission	0	0

Event Category	Event Type	No.	%
	3C - Patient suicide or attempted suicide resulting in serious disability while the patient is being cared for in a healthcare facility	0	0
Care Management Events	4A - Patient death or serious disability associated with a medication error	2	<1
	4B - Patient death or serious disability associated with a hemolytic reaction (abnormal breakdown of red blood cells) due to the administration of ABO/HLA-incompatible blood or blood products	0	0
	4C - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while the patient is being cared for in a healthcare facility	1	<1
	4D - Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	0	0
	4E - Death or serious disability associated with failure to identify and treat hyperbilirubinemia in newborns	0	0
	4F - Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	26	5
	4G - Patient death or serious disability due to spinal manipulative therapy	0	0
	4H - Artificial insemination with the wrong donor sperm or wrong egg	0	0
Environmental Events	5A - Patient death or serious disability associated with an electric shock while the patient is being cared for in a healthcare facility	0	0
	5B - Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	0	0
	5C - Patient death or serious disability associated with a burn incurred from any source while the patient is being cared for in a healthcare facility	0	0
	5D - Patient death or serious disability associated with a fall while the patient is being cared for in a healthcare facility	1	<1
	5E - Patient death or serious disability associated with the use of restraints or bedrails while the patient is being cared for in a healthcare facility	0	0
Criminal Events	6A - Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	1	<1
	6B - Abduction of a patient of any age	0	0
	6C - Sexual assault on a patient within or on the grounds of a healthcare facility	0	0
	6D - Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a healthcare facility	0	0
Healthcare Associated Infections	7 – Central-catheter-associated bloodstream infection	446	85

Event Category	Event Type	No.	%
No Event Type Reported	X - No event type reported	31	6
	Total	524	100

Reports by Level of Harm

The Department's use of NQF's list of Serious Reportable Events means that every report submitted represents an event that caused substantial harm to a patient. For example, the list does not require reporting of all patient falls or even all patient falls resulting in harm but only those resulting in "death or serious disability."⁴ There is one question on the report form that explicitly addresses the degree of harm: "Did the patient expire?" This distinguishes only two categories of harm: death or a level of harm less severe than death. Not all reportable events necessarily imply the same degree of harm, and it is often useful to distinguish among degrees of harm. To this end, a harm scale developed by the National Coordinating Council for Medication Error Reporting and Prevention was applied to non-CLABSI-related reports, 50% (39) could be categorized based on the information provided. Table 2 summarizes the level of harm among those reports. Table 3 summarizes the event types related to the 14 patient deaths reported.

Table 2. Level of Harm in Reports of Adverse Events (Excluding CLABSI)

Harm Score	Reports	%
An event occurred that contributed to or resulted in temporary harm and required treatment or intervention	7	9
An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization	16	21
An event occurred that contributed to or resulted in permanent harm	4	5
An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life)	1	1
An event occurred that contributed to or resulted in death	11	14
Could not be determined from information provided	39	50

⁴NQF defines the term "serious" as resulting "in death or loss of a body part, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient healthcare facility."

Table 3. Patient Death by Event Type

Event Type	Patient Deaths
2B - Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	1
4C - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while the mother is being cared for in a healthcare facility	1
4F - Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	4
7 - Central-catheter-associated bloodstream infection (i.e., CLABSI)	3
No event type specified	5

Reports by Healthcare Provider or Medical Facility Type

Nearly all the reports were submitted by hospitals. A nursing facility and health clinic submitted reports indicating there were no events to report. Table 4 presents the number of reports of events from each type of reporting medical facility or healthcare provider. Table 5 represents the event types reported by type of facility or provider.

Table 4. Reports by Type of Facility/Provider

Reports by Type of Facility/Provider	Total	%
Hospital	384	73.3
Long-term acute care hospital	138	26.3
Health clinic	0	0.0
Practitioner's office	1	0.2
Nursing Home	1	0.2
Total	524	100

Table 5. Event Report Types by Medical Facility or Provider

Event Type	Health Clinic	Hospital	Long-Term Acute Care Hospital	Practitioner's Office	Nursing Home	Total
1A - Surgery performed on the wrong body part	0	3	0	0	0	3
1B - Surgery performed on the wrong patient	0	1	0	0	0	1
1C - Wrong surgical procedure performed on a patient	0	1	0	0	0	1
1D - Unintended retention of a foreign object in a patient after surgery or other procedure	0	10	0	0	0	10

Event Type	Health Clinic	Hospital	Long-Term Acute Care Hospital	Practitioner's Office	Nursing Home	Total
2B - Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	0	1	0	0	0	1
4A - Patient death or serious disability associated with a medication error	0	2	0	0	0	2
4C - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	0	1	0	0	0	1
4F - Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	0	23	2	0	1	26
5D - Patient death or serious disability associated with a fall while being cared for in a healthcare facility	0	1	0	0	0	1
6A - Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0	1	0	0	0	1
7 - Central Catheter Associated Bloodstream Infection	0	310	136	0	0	446
X - No event type reported	0	30	0	1	0	31
Total	0	384	138	1	1	524

Root Causes and Corrective Action Plans in Reports

The Department of Health Adverse Event Reporting Form requires submission of a Corrective Action Plan (CAP). A CAP describes how the facility or provider plans to prevent or reduce the risk that a similar event will not occur in the future. Any CAP should be based in part on the root cause or causes of the event, defined as the most basic factor or factors that, if corrected or removed, will reduce the risk or prevent recurrence of a situation.² The provision of healthcare involves complex systems of people and technology and presents virtually unlimited opportunities for errors with many possible causes and contributing factors. Without a structured way to approach the investigation of errors, it would be easy to overlook important causative factors and miss the opportunity to put systems in place to eliminate

error. Analysis of the cause or causes of an event helps ensure that all possible causes of medical error are considered and that appropriate, effective, CAPs are developed and implemented.

Failure in the performance of any one physician, nurse, or other practitioner is seldom the sole cause of an adverse event. The investigation of the cause of an event must look beyond the direct patient care provider to identify causes embedded in the system. Through identification of the process or system vulnerability, the cause can then be eliminated through a change in the process. Four hundred and forty-six CLABSI-related reports were submitted. A sample of the 446 CLABSI-related reports submitted (43 [10%]) were individually reviewed. The reports contained only minimal data, such as demographic information and a one- or two-line event description. Six (13%) of the reviewed CLABSI reports did identify a cause. All these reports included an institutional CAP. Of the non-CLABSI-related reports submitted that specified an event type, 24 (31%) explicitly identified a cause, which suggests that adverse event investigation and root-cause analysis are areas for improvement. Of the 24 reports identifying any cause, 19 (79%) went beyond individual performance and cited one or more system-related causes for the event. Only five reports (20%) cited individual performance as one possible cause of the event. Three reports (12%) of pressure ulcers cited patient characteristics as a factor placing a patient at greater risk for the event.

Guidance and Recommendations

Adverse Events and Opportunities for Improvement

The District is charged with providing facilities and providers with recommended methods to reduce systematic adverse events and disseminating information and advice on best practices. The following is a summary of the reports submitted under each event type. As required by the Act, the information is de-identified and anonymous with regard to the facility, provider, and patient. Where required to comply with confidentiality provision of the Act, event summaries are composites of the events reported. Systems-related causes, key contributing factors, and risk reduction strategies identified in the CAPs submitted by healthcare facilities and providers are shared. Finally, recommended best practices are provided to further assist facilities and providers in improving healthcare delivery in the District.

Medical facilities submitted five reports involving wrong-site, wrong-procedure, or wrong-person surgery.

- 1A. Surgery performed on the wrong body part**
- 1B. Surgery performed on the wrong patient**
- 1C. Wrong surgical procedure performed on a patient**

Summary of Events

The patient was scheduled for a right breast biopsy, but the consent form stated the biopsy was on the left side. However, a preoperative physical exam revealed pathology on both sides. The left breast was marked by the surgeon and patient in the holding area. The discrepancy between the side marked, and the consent was verbalized by an operating room (OR) team member. The surgeon did not hear the team member state the concern, and an incision was made into the left breast. Another team member repeated the concern about the wrong side. The incision was stopped.

A patient with end-stage renal disease was scheduled to have a peripherally inserted central catheter (PICC) inserted. The documents did not indicate the side for insertion. The PICC was improperly inserted on the same side as the patient's dialysis shunt and had to be removed.

A patient developed an arrhythmia after chest surgery. The patient was scheduled to undergo insertion of a temporary pacing wire in the atrium. The wire was inserted into the patient's ventricle.

A patient with a history of spinal cord disease at multiple levels underwent a decompression of the spinal cord. The patient was discharged and readmitted several days later with complaints of persistent leg pain. An MRI revealed that the surgery had been done on the wrong spinal level.

A minor surgical procedure was performed on an infant before consent was obtained from the parents.

Key Contributing Factors

System Factors

- a) Staff deviated from the Universal Protocol (i.e., the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™).

- b) A standardized process for informed consent was lacking.

Human Factors

- a) Surgeon did not follow the customary routine during site marking.
- b) Staff did not review the patient's history or procedure card before the procedure.
- c) Caregivers became distracted.
- d) Patient agreed to marking on the wrong site.
- e) Surgeon operated on a spinal level from a previous surgery and did not use the standard method of identifying the spinal level.

Risk Reduction Strategies

Facilities shared strategies and lessons learned following the adverse events in CAPs submitted along with the reports, including the following:

- Management review of the Universal Protocol with OR and postanesthesia care unit staff
- Development of a checklist for central-catheter placement that includes exclusionary information, such as a preexisting dialysis access
- Review of the case in surgical morbidity and mortality conferences
- Presentation of a patient safety conference for all residents and hospital staff on wrong-site surgery and consent, at which the staff involved in the event presented the case
- In-service training on correct procedure verification process
- Enforcement of the "surgical pause" with physicians and nursing staff
- Review of procedure and policies on determining spinal levels
- Discussion of the procedure by the physician performing the procedure and the patient, obtaining informed consent and documenting the discussion in the progress notes
- Written orders by the physician to obtain informed consent, subsequently witnessed by the RN and signed by the physician

Additional Resources

The Joint Commission approved its Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery in 2003.⁵ More than 50 professional associations and organizations, including the American Academy of Orthopaedic Surgeons,⁶ North American Spine Society,⁷ and NQF⁸ have endorsed it. Moreover, the Universal Protocol has become part of the Joint Commission's National Patient Safety Goals.⁹

⁵ Joint Commission. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery™ [online]. [cited 2008 Sept 15]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf.

⁶ American Academy of Orthopaedic Surgeons. JCAHO Universal Protocol: universal protocol for eliminating wrong site, wrong procedure, wrong person surgery [online]. [cited 2008 Sept 15]. Available from Internet: <http://www3.aaos.org/member/safety/protocol.cfm>.

⁷ Wong DA. Spinal surgery and patient safety: a systems approach. *J Am Acad Orthop Surg* 2006 Apr;14(4):226-32.

⁸ National Quality Forum (NQF). NQF-endorsed™ serious reportable events in healthcare: 2006 update [online]. [cited 2008 Sept 15]. Available from Internet: <http://216.122.138.39/pdf/news/txSREReportAppeals10-15-06.pdf>.

⁹ Joint Commission. Facts about the National Patient Safety Goals™ [online]. 2008 June [cited 2008 Sept 15]. Available from Internet: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/faqs_2008_npsg.htm.

Elements of the Joint Commission’s Universal Protocol include a standardized approach for the following:

- Verifying the patient’s identity
- Marking the surgical site and requiring patients or a legally designated representative to be involved in the marking procedure
- Using a preoperative site verification process, such as a checklist
- Confirming the availability of appropriate documents and studies before the start of the procedure
- Taking a brief time-out immediately before skin incision, in which all members of the surgical team actively communicate and provide oral verification of:
 - patient identity
 - surgical site
 - surgical procedure
 - administration of preoperative medications
 - presence of appropriate medical records, imaging studies, and equipment
 - monitoring compliance with protocol recommendations

The protocol is designed to be flexible so that it can be adapted to meet specific patient needs, operations, and other invasive procedures, including those performed in settings other than the OR. The Universal Protocol is organized into three phases, as follows:^{7,10,11}

1. Preoperative verification process. In this phase, all relevant documents/studies are available for review for consistency with each other, the patient’s expectations, and the surgical team’s understanding of the patient, procedure, site, and implants. Missing information/discrepancies are resolved before continuing. Ongoing information gathering and verification occurs from determination to do the procedure through the time-out.
2. Marking the operative site. For left/right distinction, multiple structures, and multiple levels, the intended site is marked so that the mark is visible after the patient is prepped and draped. The site is marked unambiguously. The site should be marked by a person performing the procedure either with his/her initials or “yes”—never with an “X”; the patient should never be marked on a nonoperative site; and the site should be marked and numbered for multiple wounds/lesions. The mark should be visible after the patient is prepped and draped.
3. Time-out should be observed immediately before starting the procedure. This phase includes final verification of the correct patient, procedure, and site. The phase is initiated by a designated team member. Active communication occurs among all surgical/procedure team members. Finally, the procedure is not started until questions/concerns are resolved. The time-out includes a check for the presence of

¹⁰ Pennsylvania Patient Safety Authority. Doing the “right” things to correct wrong-site surgery. *PA PSRS Patient Saf Advis* 2007 Jun;4(2):1-17.

¹¹Joint Commission. Implementation expectations for the Universal protocol for preventing wrong site, wrong procedure, wrong person surgery™ [online]. 2003 [cited 2008 Sep 28]. Available from the Internet: http://www.jointcommission.org/NR/rdonlyres/4CF3955D-CD1F-4230-86C5-D04485CAFBEA/0/IG_final.pdf.

implants, special equipment, and instruments. Procedures done at the bedside require marking and a time-out.

The following are exempt from the preoperative marking process but must still have a time-out:

- Single-organ procedures
- Interventional procedures with sites/insertions that are not predetermined and can be either left or right
- Procedures on premature infants

Failure to obtain consent for a procedure was reported as a contributing factor to the wrong procedure—or, more specifically in this case, an *unwanted* procedure—being performed on an infant. NQF has suggested safe practices related to the informed consent process. Institutional policies on informed consent should contain the following elements:¹²

- Which type of procedures, treatment, or services require informed consent
- What process is used to obtain informed consent
- How informed consent is to be documented in the record
- When a surrogate decision maker, rather than the patient, may give informed consent
- When procedures or care, treatment, and services normally requiring informed consent may be given without informed consent

1D. Retention of a Foreign Object

Summary of Events

Incorrect sponge counts:

During an emergency surgery, a sponge count was not performed due to the emergent nature of the surgery. Multiple sites of bleeding were packed with sponges. The packing was to remain in place until reexploration the following day. Following reexploration, the surgeon and radiologist interpreted the x-ray as negative for retained foreign objects. During a subsequent planned reexploration, several sponges were found in the patient's right upper abdomen and removed.

A patient underwent an exploratory laparotomy. The initial sponge count was correct. There were two changes of members of the surgical team, after which a repeat count was correct. The patient's recovery was uneventful until three days postoperatively, when a chest x-ray revealed a foreign object. The patient underwent a second surgery, and a sponge was removed from behind the liver.

A patient underwent a chest surgery. The sponge counts were correct at the completion of the surgery. After the patient's condition deteriorated a week later, the patient was returned to the OR and a surgical sponge was removed from the patient's chest cavity.

¹²National Quality Forum (NQF). Safe practices for better healthcare 2006 update [online]. [cited 2008 Sept 15]. Available from Internet: <http://www.qualityforum.org/pdf/projects/safe-practices/SafePractices2006UpdateFINAL.pdf>.

A patient underwent an arthroscopy. The surgical counts were correct. An x-ray taken after discharge showed a retained foreign object. A surgical procedure was performed to remove a surgical sponge.

Retained foreign objects:

A guide wire fractured during an interventional radiology procedure. After multiple attempts, the fragment could not be removed. The patient experienced extended exposure to fluoroscopy during the attempt to retrieve the wire fragment.

During a laparoscopy procedure, a needle used for suturing became detached from the suture and fell into the patient's abdomen. Examination of the abdomen with x-ray and fluoroscopy did not reveal the needle, and the operation was completed. A postoperative CT scan of the abdomen revealed the needle, which was removed during a surgical procedure the following day.

During a laparoscopy procedure, a needle became detached from the suture. An examination and intraoperative x-rays did not reveal a foreign body, and the procedure was completed. A postoperative x-ray later that day revealed the needle. The patient underwent a laparoscopic exploration and removal of the needle.

A patient had a central intravenous line placed before surgery. The internal guide wire used in catheter insertion accidentally was not removed. A postoperative chest x-ray revealed the guide wire. The patient was taken to interventional radiology for removal of the guide wire.

A central venous catheter was placed before surgery. A postoperative chest x-ray showed a guide wire in the inferior vena cava, which was removed.

During a hysterectomy, the sheath portion of a uterine manipulator was left in the patient's vagina. It was discovered when the patient had difficulty voiding; the sheath was removed by the physician.

Key Contributing Factors

System Factors

- a) There was no initial briefing of the team.
- b) Actual counts may not have been done when team members were relieved by other staff during the procedure.
- c) There may potentially be a variation in the amount of radiopaque material used in manufacture of sponges.

Human Factors

- a) The physician failed to remove the guide wire.
- b) A sponge may have been counted that was not in the count bag.
- c) The attention of the attending physician was focused on one part of a procedure during the training of a physician, and it was an oversight that the foreign object was left in the patient.

Risk Reduction Strategies

Facilities shared strategies and lessons learned following the adverse events in CAPs submitted along with the reports, including the following:

- a) The facility's standard practice was amended to include direct communication between the surgical team and the radiologist regarding the type of object, location, and presence of other equipment or devices when retention of a foreign object is suspected.
- b) The OR team underwent situational awareness training.
- c) The OR counting policy was reviewed with staff, and human factors that may have accounted for the erroneous correct sponge count were discussed.
- d) The policy regarding staff response to an equipment failure during a procedure was reviewed and updated.
- e) A policy was developed requiring that all x-rays to rule out the retention of a foreign body during abdominal surgeries must include both the base of the lung and the pubic rami.
- f) The practice of always checking central line placement postoperatively by obtaining an x-ray will be reinforced to prevent the retention of a guide wire.
- g) A vascular access device insertion sticker will be placed on the patient's chart and will be completed postprocedure. The sticker will indicate that the guide wire was removed.
- h) All radiology request forms will specify when an x-ray is being performed to confirm central line placement.

Additional Resources

In July 2006, the Association of periOperative Nurses (AORN), with the support of the American College of Surgeons, published the following best practices for preventing the retention of a foreign object:^{13,14}

- Consistently performing surgical counts according to national standards and facility policy
- Promoting an environment that is focused on, and attentive to, the patient's perioperative care
- Using only x-ray-detectable sponges, towels, miscellaneous items, and instruments in the surgical wound
- Conducting a methodical wound exploration before wound closure and whenever a count discrepancy is noted
- Employing radiographic or other technology as needed to ensure that all potential foreign objects have been removed from the surgical site
- Documenting the outcomes of the surgical count, items intentionally used for packing, and actions taken to rectify a count discrepancy
- Providing resources to support safe practices to prevent retention of foreign objects
- Developing and reviewing count policies and procedures through a collaborative process to promote consistency in practice across disciplines
- Making count policies and procedures readily available in the practice setting

¹³ Association of periOperative Nurses (AORN). Best practices for preventing a retained foreign body. *AORN J* 2006 Jul;84(1 Supp 1):S30-6.

¹⁴ American College of Surgeons. Statement on the prevention of retained foreign bodies after surgery. *Bull Am Coll Surg* 2005 Oct;90(10):15-6.

AORN's recommended practices for sponge, sharp, and instrument counts may be adapted to various practice settings, including interventional radiology (IR). The following actions are additional policy considerations applicable to this setting:¹⁵

- Perform a count of surgical sponges, sharps, and other miscellaneous items on all IR cases in which the possibility exists that an item could be retained. This includes all procedures that involve a surgical pocket.
- Use x-ray-detectable sponges in all cases that involve a surgical pocket.
- Count items during IR procedures involving a surgical pocket at the following times:
 - before incision to determine baseline,
 - at the time of permanent relief of scrub or circulator, and
 - at the closure of pocket/incision closure.
- Count any item added to the surgical field.
- Separate sponges to allow viewing of the sponge and the x-ray-detectable strip.
- Notify the performing operator to inspect the surgical pocket and confirm the absence of a retained foreign object with x-ray in the event of a count discrepancy.

2B. Patient Death or Serious Disability Associated with the Use or Function of a Device

Summary of Event

After surgery while in recovery, the patient experienced respiratory distress and required intubation. During the intubation, the wall suction was not operational.

Key Contributing Factors

System Factors

- a) Nonfunctioning wall suction apparatus

Human Factors

- a) Inadequate communication during code situations

Risk Reduction Strategies

The facilities shared strategies and lessons learned following the adverse event in a CAP submitted along with the report, including the following:

- a) Portable suction equipment will be standard issue on all nursing units.
- b) Communication will be facilitated during code situations by using a hands-free voice communication system.

¹⁵ Pennsylvania Patient Safety Authority. Preventing the retention of foreign objects during interventional radiology procedures. *PA PSRS Patient Saf Advis* 2008 Mar;5(1):24-7.

Additional Resources

Malfunctioning equipment, such as a wall suction device, is a patient safety hazard addressed by Joint Commission standards. The Joint Commission defines requirements for safety management in its Environment of Care standards; these requirements include providing “a safe, functional, supportive, and effective environment for individuals served, staff members, and other individuals in the organization.”² Safety management programs in healthcare facilities must encompass the entire healthcare environment and all the hazards it contains, including maintenance of the wall suction. An effective safety management program not only ensures regulatory compliance but also a safe environment for patients and staff. A healthcare facilities safety manual should include detailed policies and procedures that support the program. Key elements to include in a safety management program are summarized below.¹⁶

- Security
- Hazardous materials and waste management
- Emergency management
- Fire and life safety
- Medical equipment management
- Infection control
- Utility systems management

The submitted report involves a medical vacuum system, a device that would be addressed in the utility system management component of a safety management program. Additional elements to consider specific to medical gas and vacuum systems (MGVSs) in a utility systems management policy include the following:¹⁷

- Perform inspection and testing of the MGVS at regular intervals, including pressure testing to ensure that there is no leakage and that the alarms activate.
- Ensure that there is an adequate supply of appropriate connectors and tubing to avoid the likelihood of tubing misconnections to MGVSs.
- Ensure proper labeling, color coding (e.g., of outlets, fittings, hoses, and manifolds), standardization of outlet type, and education of all facility staff about MGVSs to minimize the likelihood of an improper connection.
- Ensure that the facility has an emergency response plan that details the actions to take if the MGVS fails. Staff members should be able to recognize alarms associated with the MGVS and should know how to respond when they occur.
- Ensure that alternate vacuum sources, such as portable suction devices, are strategically located to be quickly available for use.

¹⁶ ECRI Institute. Safety management. *Healthc Risk Control* 2006 Sep:2:Safety and Security 2:1-8.

¹⁷ ECRI Institute. Medical gas and vacuum systems. *Healthc Risk Analysis* 1996 Jan:3 Environmental Issues 17:1-18.

4A. Patient Death or Serious Injury Associated with a Medication Error

Summary of Events

A patient on anticoagulation therapy underwent neck surgery. A heparin drip was stopped the morning of the patient's surgery and resumed postoperatively. Two nurses verified the rate of infusion, and the pump was programmed. A technician went in to the room to obtain intake and output measurements and possibly cleared the settings and information on the infusion pump. The infusion bag was discovered nearly empty several hours later ahead of schedule. The patient developed a hematoma of the neck and was returned to the OR for evacuation of the hematoma. He underwent an emergency tracheostomy several hours postoperatively.

During a major surgery, the anesthesiologist picked up a vial and directed a medical student to withdraw and administer to the patient what he believed was Decadron. The patient became hypertensive and tachycardic. The patient's condition continued to deteriorate, and chest compressions were started. The anesthesiologist realized that the patient had received Levophed instead of Decadron. As a result of the code, the patient sustained fractured ribs and a liver hematoma.

Key Contributing Factors

System Factor

- a) Medication vial labels were similar in color and appearance.

Human Factors

- a) Inadequate frequency of monitoring of the infusion pump
- b) Failure to read the medication label
- c) Failure to double-check medication before administration

Risk Reduction Strategies

Facilities shared strategies and lessons learned following the adverse events in CAPs submitted along with the reports, including the following:

- a) The role of staff members in clearing settings on infusion pumps was clarified. Technicians will no longer change settings on infusion pumps.
- b) A multidisciplinary meeting was held to review the current heparin order sheet, the anticoagulation flow sheet, current standardized heparin bags, and safety checks.
- c) A formal, mandatory in-service was held for anesthesia providers on medication verification.
- d) Pharmacy reviewed available premixed induction medications to identify potentially confusing labels and make recommendations or changes to labeling and practices as required.

Additional Resources

Numerous factors in the healthcare delivery system may contribute to medication errors. Errors can occur with any medication and at any point in the medication use process and in any care setting. Practices known to be effective in preventing medication errors are summarized below.¹⁸

- Healthcare organizations must reconcile and accurately communicate an accurate medication list throughout the continuum of care.²
 - The Joint Commission requires that a complete list of the patient’s medications be obtained at the beginning of each episode of care. At a minimum, reconciliation must occur any time orders are required to be rewritten and any time the patient changes service, setting, provider, or level of care.
- Utilize a systems approach with a multidisciplinary focus to ensure that medications are used in a safe and effective manner.²
 - Pharmacists should actively participate in medication management systems and selection of a safe and effective formulary, as well as be available for consultation with other healthcare providers; for interpretation and review of medication orders, safe storage, and dispensing of medications; and for administration and monitoring of medications.
- Ensure that systems are in place to optimize proper labeling and packaging of medications.²
 - To help minimize errors related to nomenclature, labeling, and packaging, consider the following strategies:
 - a) Perform a failure mode and effects analysis before adding a medication to the organization’s inventory in order to identify potential pitfalls, such as look-alike labels.
 - b) Review reports from external sources to identify error-prone medications.
 - c) Purchase from different vendors to prevent look-alike labels.
 - d) Separate and clearly differentiate products that are similar.
- Ensure the safe use of high-alert drugs.
 - Apply human factors principles to simplify processes by reducing the number of steps and options available for the handling of high-alert medications such as heparin.
 - Provide fail-safes such as infusion pump drug library hard stops, default settings, and free-flow protection.
- Reduce adverse events from bulk packaging of medications by dispensing medications in unit-dose or unit-of-use form.

4C. Maternal Death or Serious Disability Associated with Labor or Delivery in a Low-Risk Pregnancy

Summary of Event

A patient underwent a cesarean section and was transferred to the intensive care unit (ICU) due to hypotension possibly related to bleeding. The patient received multiple blood products. Her condition deteriorated, and she developed a coagulopathy. The patient suffered a cardiac arrest. She was

¹⁸ Pennsylvania Patient Safety Authority. Drug labeling and packaging—looking beyond what meets the eye. *PA-PSRS Patient Saf Advis* 2007 Sep; 4(3):1-6.

resuscitated and underwent a total abdominal hysterectomy. She was transferred to the neurological ICU.

Key Contributing Factors

System and human factors were not identified in the report. Contributing factors to errors leading to perinatal injury and death have been identified as a lack of or insufficient plan of action, unavailability of monitoring equipment and/or drugs, unclear expectations or identification of responsibilities of staff members, and lack of effective communication among team members.¹⁹

Risk Reduction Strategies

The facility did not identify risk reduction strategies.

Additional Resources

This report identifies that excessive bleeding following a cesarean delivery may have been the underlying cause of the patient's hypotension and subsequent cardiac arrest. Postpartum hemorrhage is an obstetric emergency that can follow a vaginal or cesarean delivery. It is a major cause of maternal death, with serious outcomes such as shock, renal failure, acute respiratory distress syndrome, coagulopathy, and pituitary necrosis.²⁰ Many risk factors are associated with postpartum hemorrhage; however, it often occurs without warning. Obstetrics units and practitioners can use the following strategies to prepare for and manage this emergency.

In 2004, the Joint Commission issued a risk reduction strategy for decreasing perinatal death or permanent disability related to shoulder dystocia, emergency cesarean section, and maternal hemorrhage. Recognizing that the majority of perinatal death and injury cases are related to problems with organizational culture, the Joint Commission recommends strategies for organizations, including the following:¹⁹

- Conduct team training to facilitate effective team communication.
- Conduct clinical drills to help staff prepare for these events.
- Conduct debriefings following adverse events to evaluate team performance, and identify areas for improvement.
- Review and apply American College of Obstetricians and Gynecologists (ACOG), Association of Women's Health, Obstetric and Neonatal Nurses, and American Academy of Pediatrics guidelines for perinatal care.

Additional system approaches to the management of obstetric hemorrhage have been suggested and include the following elements:²¹

¹⁹ Joint Commission. Preventing infant death and injury during delivery. Sentinel Event Alert No. 30 [online]. 2004 July [cited 2008 Sept 18]. Available from Internet: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_30htm.

²⁰ American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin: Clinical management guidelines for obstetrician-gynecologists. Number 76. October 2006: Postpartum hemorrhage. *Obstet Gynecol* 2006 Oct;108(4):1039-47.

²¹ Ogburn P. Obstetric hemorrhage [slideshow online]. [cited 2008 Sept 19]. Available from Internet: http://www.health.state.ny.us/professionals/protocols_and_guidelines/maternal_hemorrhage/docs/stony_brook_obstetric_hemorrhage_presentation.ppt.

- Education
 - Simulation drills to assist staff with preparing for emergencies and identifying system issues
 - Monthly debriefings to review responses to simulations and real events and identify areas of strength and areas needing improvement
- Preparation
 - Standard admission orders for labor and delivery
 - Standard orders for obstetric hemorrhage
 - Maternal fetal medicine supervision for the first 24 hours after initiation of the emergency
 - Appropriate equipment
 - Appropriate training
- Vigilance
 - Application of a system of orders, training, and monitoring
- Persistence
 - Mandated 24-hour monitoring following a hemorrhagic event
- Continuous improvement

A 2006 ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists Number 76, provides clinical guidelines regarding the etiology, evaluation, and management of postpartum hemorrhage.²⁰

4F. Stage III or IV Pressure Ulcers Acquired after Admission to a Healthcare Facility

Summary of Events

The Department has received 26 reports of stage III or IV pressure ulcers acquired after admission. The majority of these reports (21 [80%]) were submitted by hospitals. One report was submitted by a skilled nursing facility, two by a hospital, and two by a long-term acute care hospital. Eighteen reports (64%) involved patients over age 65. The most frequently cited comorbidities in patients who developed pressure ulcers were poor nutritional status, severe anemia, and obesity. The following is a sample of the reports.

A ventilator-dependent patient was admitted for mental status changes. The patient was assessed to be at high risk for pressure ulcers on the admission assessment. The patient was minimally responsive and bedridden. The patient developed stage III pressure ulcers on the toes and foot.

An elderly patient with multiple comorbidities was admitted and taken to the OR for repair of a bowel perforation. The patient was transferred to the medical ICU and developed a pressure ulcer approximately three weeks postoperatively.

An elderly patient was admitted with a subdural hematoma. The patient had skin breakdown on admission and was assessed at high risk for further breakdown. The patient underwent surgery on the day of admission. Wound care was ongoing on multiple areas of breakdown. Stage I pressure ulcers on the patient's lower extremity progressed to stage III.

An elderly patient was admitted with suspected meningitis. The patient developed a gastrointestinal bleed and was transferred to the medical ICU. The patient underwent surgery for a perforated bowel. A pressure ulcer was discovered a week after surgery.

A patient developed a stage III pressure ulcer at the site of a tracheostomy.

Key Contributing Factors

System Factors

- a) Prolonged ICU admission

Human Factors

- a) Less focus was placed on patient positioning in the immediate postoperative period because the care team was focused on positioning for maximum aeration.
- b) Staff missed the signs of early skin breakdown.

A number of the reports indicated that the staff followed all policies and procedures for pressure ulcer prevention and care. Appropriate use of ancillary services, including nutrition and wound care services, was also noted.

Risk Reduction Strategies

Facilities shared strategies and lessons learned following these adverse events in CAPs submitted along with the reports, including the following:

- a) All bed surfaces were replaced hospitalwide with mattresses with pressure redistribution.
- b) Wound care protocols were revised to include all phases of skin breakdown.
- c) Weekly interdisciplinary wound care rounds were held to discuss plans of care for all patients with wounds.
- d) The formulary for skin care products was standardized, and staff were trained on product use.
- e) A wound care intranet resource was made available to staff.
- f) A skin resource group meets monthly to improve pressure ulcer care and management; unit champions attend and are liaisons to the clinical units.

Additional Resources

Prevention of pressure ulcers is the goal of every healthcare facility. Recognized risk scales by the National Pressure Ulcer Advisory Panel (NPUAP) are the Braden, Norton, and Gosnell scales.²² Each scale provides a means for assessing and calculating a patient's risk. Based on the determined risk score, appropriate preventive interventions are implemented. Any change in the patient's condition requires a reassessment. The Braden Scale for Predicting Pressure Ulcer Risk is considered the most widely used tool for predicting the development of pressure ulcers.²³ A current definition of the stages of pressure ulcers can be found at the NPUAP Web site, including the following:²⁴

²² National Pressure Ulcer Advisory Panel (NPUAP). Pressure ulcer prevention: A competency-based curriculum [online]. 2001 [cited 2008 Sep 17]. Available from Internet: <http://www.npuap.org/PDF/prevcrr.pdf>.

²³ Ayello E, Braden B. How and why to do pressure ulcer risk assessment. *Adv Skin Wound Care* May/Jun 2002;15(3):125-32.

- **Suspected deep-tissue injury:** Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler compared to adjacent tissue.
- **Stage I:** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.
- **Stage II:** Partial thickness loss of dermis, presenting as a shallow open ulcer with a red/pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.
- **Stage III:** Full-thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
- **Stage IV:** Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. May often include undermining and tunneling.
- **Unstageable:** Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

A number of clinical practice guidelines have been developed in the area of pressure ulcer prevention and treatment. The following is a summary of the National Quality Forums' Safe Practices for Pressure Ulcer Prevention:¹²

- Evaluate each patient on admission and regularly thereafter for the risk of developing pressure ulcers.
- Implement explicit organizational policies regarding the prevention of pressure ulcers, including the following:
 - Identify individuals at risk of developing pressure ulcers.
 - Document the pressure ulcer risk assessment and prevention plan.
 - Assess and periodically reassess each patient's risk, and act on the assessment.
 - Perform quarterly prevalence studies to evaluate the effectiveness of the pressure ulcer prevention program.
- Performance improvement initiatives should include the following elements:
 - Education regarding the pertinent pressure ulcer frequency and severity
 - Skill building in use of pressure ulcer prevention interventions
 - Implementation of process improvement interventions
 - Measurement of process or outcome indicators
 - Reporting of performance outcomes

NQF also endorses the use of example implementation approaches, as follows:¹²

- Use of preventive fire-code-compliant pads or plastic polymer pressure-relieving pads on pressure points
- Repositioning of any patient at risk for the development of a pressure ulcer at least every two hours

²⁴ National Pressure Ulcer Advisory Panel (NPUAP). Updated staging system [online]. 2007 [cited 2008 Sep 16]. Available from Internet: <http://www.npuap.org/pr2.htm>.

- Nutrition assessment and supplements when indicated
- Instituting a protocol incorporating specific risk assessment scores, and empowering nurses to initiate prevention interventions without a physician's order

A summary of pressure ulcer prevention guidelines may be found at the National Guideline Clearinghouse (www.guideline.gov). In addition, NPUAP provides a list of pressure ulcer prevention points at http://www.npuap.org/PU_Prev_Points.pdf.

5D. Patient Death or Serious Disability Associated with a Fall

Summary of Event

The patient was medicated with a combination of Haldol, Ativan, and Benadryl in the morning. She was instructed not to shower. Security staff heard a thump three hours later but did not tell the charge nurse. Several minutes later, the charge nurse noticed a bump on the patient's forehead. The patient stated she fell. A computerized axial tomography (CAT) scan of the head showed a subdural hematoma. The patient underwent surgery for evacuation of the hematoma.

Key Contributing Factors

System Factors

- a) None identified

Human Factors

- a) Failure to notify supervisor of an unusual occurrence

Risk Reduction Strategies

Facilities shared strategies and lessons learned following the adverse event in a CAP submitted along with the report, including the following:

- a) Review policy regarding the use of combinations of sedative medications with staff.
- b) Ensure that staff follow chain-of-command policy, and document who was contacted.
- c) Revise policy requiring that vital signs be taken before administration of sedative medications.
- d) Provide education to each shift.

Additional Resources

More than 1.8 million falls occur nationally every year; the most common injury is a hip fracture.²⁵ Accordingly, understanding falls risk and prevention, developing effective policies and procedures, and establishing a falls prevention program are essential.²⁶ Since 2005, the Joint Commission's National Patient Safety Goals for accredited organizations have included the implementation of a program aimed at reducing the risk of injury from falls. To meet the requirements for this goal, accredited facilities must implement falls reduction programs and conduct ongoing assessment of the efficacy of the program. The key components of a program aimed at addressing the persistent problem of falls in healthcare

²⁵ ECRI Institute. *Falls Prevention Strategies in Healthcare Settings*. Plymouth Meeting (PA): ECRI Institute; 2006 Oct.

facilities include assessment for falls risk, action-based interventions, postfalls assessment and data collection, and use of falls reduction program tools.²⁶ When developing or revising fall prevention policies and protocols, it is important to consider that the risk factors for falls are complex and that no single type of intervention will succeed in eliminating the risk of falling.

Major areas that should be addressed in a falls prevention policy include the following:^{26,27}

- Composition, responsibilities, and goals of a falls prevention team
- Definition of a fall
- Falls risk assessment requirements for inpatients, residents, outpatients, visitors, and employees
- Requirements for reassessment of risk
- Environmental rounds
- Responsibilities of staff
- Initial and ongoing education of staff
- Intervention strategies
- Appropriate responses to falls, including protocols for investigation
- Event documentation and reporting requirements
- Collection and analysis of data for trends
- Revision of intervention strategies based on data
- Falls rates reporting within a quality improvement plan
- Promotion of the falls reduction program and risk awareness
- Reeducation of caregivers who are noncompliant with falls policies, procedures, and protocols, as well as counseling or remediation should noncompliance persist

In this report, the patient's medication management was a contributing factor to the patient's fall. Including the patient's medications in a falls risk assessment is critical since certain medications greatly increase the risk of falling.²⁷ Serotonin-reuptake inhibitors, tricyclic antidepressants, neuroleptic agents, benzodiazepines, anticonvulsants, and class 1A antiarrhythmic medications have been strongly linked to an increased risk of falling.²⁸ The Agency for Research and Quality (ARHQ) provides numerous guidelines for the prevention of falls.²⁹ Examples of strategies related to medications that may be implemented to prevent falls include the following:³¹

- Review current medications.
- Review over-the-counter medications, dietary supplements, and recreational drug use.
- Review alcohol consumption.
- Monitor for recent changes in medication regimen.
- Monitor for drug side effects, such as drowsiness, dizziness, daytime sedation, changes in bowel or bladder function, impaired balance, and hypotension.

²⁶ ECRI Institute. Falls. *Healthc Risk Control* 2005 Sep;2:Safety and Security 2:4-6.

²⁷ Pennsylvania Patient Safety Authority. Medication assessment: one determinant of fall risk. *PA PSRS Patient Saf Advis* 2008 Mar;5(1):16-8.

²⁸ Joint Commission. Root causes: tips and strategies for addressing the top three root causes of falls. *Jt Comm Perspect Patient Saf* 2003 Jun;5.

²⁹ Association for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse: Fall prevention in older adults [online]. 2004 Feb [cited 2008 Sep 19]. Available from Internet:

http://www.guideline.gov/summary/summary.aspx?doc_id=4833&nbr=003480&string=fall+AND+prevention.

- Monitor for polypharmacy: taking more than three or four medications a day increases the risk for falls.

A number of fall prevention tools can be found at AHRQ's Quality Tools Web site at <http://www.qualitytools.arhq.gov>.

6A. Any Instance of Care Ordered by or Provided by Someone Impersonating a Physician, Nurse, Pharmacist, or Other Healthcare Provider

Summary of Event

The program director for a residency program was informed that a candidate had failed to meet all requirements to be eligible to participate in the National Residency Match Program. The involved individual was removed from the training program. Review of patient contacts from the individual's start date indicated evidence of adverse patient impact; however, evidence not specified in the report.

Key Contributing Factors

System Factors

- a) None identified

Human Factors

- a) Failure of program director to complete verification process due to staffing concerns

Risk Reduction Strategies

Facilities shared strategies and lessons learned following the adverse events in CAPs submitted along with the reports, including the following:

- a) Primary source verification of graduation will be obtained from the candidates for U.S. graduates of the Educational Commission for Foreign Medical Graduates.
- b) Proof of graduation or certification for foreign medical graduates has been added to staff eligibility criteria.

Additional Resources

Under the Medicare Conditions of Participation, Joint Commission standards, and many state laws, hospitals are required to investigate the credentials of a physician before allowing the physician to practice in the hospital. In 2007, the Joint Commission strengthened and extended the medical staff credentialing process.³⁰ Joint Commission Standard M.S.4.30 now requires a "focused evaluation" as part of an intense assessment of a healthcare practitioner's credentials and competence. The focused evaluation is an intense review of a practitioner's credentials and current competence. It applies to new medical staff applicants and current practitioners who request new privileges and is in force when the hospital has no evidence of a practitioner's competence. It also applies to practitioners with negative performance evaluations or those falling short of the volume of cases required for assessing practice

³⁰ Joint Commission. *Comprehensive accreditation manual for hospitals*. Oakbrook Terrace (IL): Joint Commission Resources; 2006.

competence. The hospital must check with primary sources to determine whether the practitioner requesting medical staff membership and privileges has the requisite current training, knowledge, skills, and abilities.

The standard also requires ongoing professional practice evaluation beyond case-by-case peer review. Hospitals and clinics now must supplement traditional evaluation practices with reliable outcome and performance data.

Additional credentialing policy and procedure considerations include the following:³¹

- Review medical staff bylaws to ensure that the credentialing criteria and process for initial appointment, reappointment, and clinical privileges (including temporary, expedited, and disaster privileges) is stated clearly and complies with Joint Commission standards, state and federal regulations, and court decisions.
- Ensure that peer-review and credentialing processes are conducted in accordance with medical staff bylaws and that the bylaws are made available to all medical staff members and applicants and all applicants for initial appointments, reappointments, and/or clinical privileges.
- Ensure that primary source verification or the accepted equivalent is obtained to verify information provided by a practitioner on his or her application.
- Retain an independent credentialing expert when it is not feasible for staff members to objectively investigate and review the professional activities of an applicant or currently credentialed practitioner.
- Ensure that processes have been established and used consistently to determine practitioner competency (including the health status of the practitioner) for clinical privilege requests, especially with regard to new technology and procedures.
- Ensure that applicants receiving temporary or expedited privileges have “clean” applications. Clean applications are defined as those submitted by practitioners with no current or previously successful challenge to license or registration, no involuntary termination of membership from a medical staff, and no involuntary limitations, reduction, denials, or losses of clinical privileges at another institution.

7. Nosocomial Infection Defined as a Central-Catheter-Associated Laboratory-Confirmed Primary Bloodstream Infection

Summary of Events

The Department received 446 reports of CLABSIs. Hospitals reported 396 (88%) of CLABSI-related events; 336 (85%) of those reports were submitted by one hospital. The remainder were reported by long-term care facilities. In almost all of the reports, the event descriptions provided included only a statement that the patient developed CLABSI and blood cultures were obtained; no further details were provided. For example:

- Blood cultures were drawn and grew *Enterococcus faecium*. The patient had multiple central lines.

³¹ ECRI Institute. Medical staff credentialing. *Healthc Risk Control* 2005 July;3 Medical Staff 1:17,18.

- The patient developed a CLABSI after a small bowel resection. The patient had a central line in place.
- The patient developed a CLABSI with a PICC line in place. The patient underwent a sacral wound debridement.

Nationally, the incidence (or infection rate) of CLABSI in hospitals ranges from 1.5 to 6.8 infections per 1,000 central-line days, depending on the type of hospital unit.³² To compare the CLABSI rate in District of Columbia hospitals with national figures requires collecting data not only on the infections, but also on the number of patients in each facility that have central line catheters during the same time period. During the first annual reporting period the Department did not require facilities to report this information. District healthcare providers recommend collection of denominator data utilizing central-line days to standardize the reporting of CLABSIs. The Department is considering whether to collect this information from hospitals through the Centers for Disease Control and Prevention's National Health Surveillance Network, a web-based infection reporting system for hospitals.

District healthcare providers recommend clarification of the definition and reporting criteria for CLABSI. Some institutions are conducting housewide surveillance, while other medical centers are only collecting data from the ICU, demonstrating the disparity in reporting. The Board of Medicine, together with the Department of Health's Health Regulation and Licensing Administration, will review the definition of CLABSI with a view toward redefining the reporting criteria, and will convene an advisory group to assist in developing a strategic plan addressing the recommendations of the various reporting healthcare providers.

Key Contributing Factors

System and human factors were not specified in the reports; however, known contributing factors to CLABSI are poor catheter handling techniques, unsanitary treatment areas, and lack of proper hand washing.

Risk Reduction Strategies

The majority of reports included an institutional CAP, which included the following:

- a) Collection of CLABSI data according to U.S. Centers for Disease Control and Prevention (CDC) guidelines.
- b) Documentation and monitoring of central line use.
- c) Removal of unnecessary lines to minimize a potential source of infection.
- d) Skin disinfection with chlorhexidine skin preparations before central line insertion.
- e) Educational programs, including dressing care and manikin-based simulation.
- f) Carts and kits with standardized equipment for central line insertion to make necessary supplies readily available.

³² Edwards JR, Peterson KD, Andrus ML, et al. National Healthcare Surveillance Network (NHSN) Report, data summary for 2006, issued June 2007. *Am J Infect Control.* 2007 Jun;35(5):290-301.

Additional Resources

NQF promotes safe practices based on both CDC and Institute for Healthcare Improvement recommendations, summarized below:^{14,33,34}

- Perform hand washing using an alcohol-based hand rub before and after central catheter insertion and during catheter care.
- Use maximal barrier precautions in preparation for central-catheter insertion.
 - Cover the patient from head to toe with a sterile drape with an opening for the insertion site and using a cap, mask, sterile gown, and sterile gloves.
- Perform skin antiseptics using a 2% chlorhexidine-based preparation before catheter insertion.
 - Apply chlorhexidine solution using a back-and-forth friction scrub for at least 30 seconds.
 - Allow antiseptic solution time to dry completely before puncturing the site.
- Select the optimal site for catheter insertion.
 - A subclavian line is the preferred site for nontunneled central catheters in adults.
- Review line necessity daily, and remove unnecessary lines promptly.
- Replace catheter site dressings according to CDC guidelines, as follows:³²
 - Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site. Tunneled central venous catheter sites that are well healed might not require dressings.
 - If the patient is diaphoretic, or if the site is bleeding or oozing, a gauze dressing is preferable to a transparent, semi-permeable dressing
 - Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled.
 - Change dressings at least weekly for adult and adolescent patients, depending on individual patient circumstances.
 - Do not use topical antibiotic ointment or creams on insertion sites (except when using dialysis catheters) because of their potential to promote fungal infections and antimicrobial resistance.
 - Do not submerge the catheter under water. Showering should be permitted when precautions can be taken to reduce the likelihood of introducing organisms into the catheter.

³³ O'Grady NP, Alexander M, Dellinger EP, et al. Guidelines for the prevention of intravascular catheter-related infections. Centers for Disease Control and Prevention. *MMWR Recomm Rep* 2002 Aug 9;51(RR10):1-26. Also available: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm>.

³⁴ Institute for Healthcare Improvement (IHI). Prevent central line infections. Getting started kit. Updated how-to guide [online]. 2008 Jun [cited 2008 Sept 17]. Available from Internet: <http://www.ihl.org/IHI/Programs/Campaign/CentralLineInfection.htm>.

Conclusion

Medical facilities and providers in the District have taken an important step in reducing the number of adverse events by submitting adverse event reports under the Medical Malpractice Amendment Act of 2006. Of the 15 licensed hospital facilities in the District, inclusive of long-term acute care hospitals, 10 facilities submitted a report. Two licensed nursing homes submitted a report out of 21 licensed facilities, one of the nursing homes submitted a report indicating there were no events. A health clinic and a practitioner's office also submitted reports. No other medical facilities or providers have submitted reports, possibly indicating a lack of reportable events. However, it may also represent an opportunity for improvement at those facilities. No submitted reports included identifying patient or provider information within the body of the report.

The success of any reporting program relies in large part on the willingness of healthcare facilities and providers to submit meaningful reports. Of the 47 non-CLABSI event reports submitted that included an event type, 40 (85%) were substantially complete and included almost all requested demographic information. Thirty-four (72%) of the non-CLABSI reports included relevant patient comorbidities. Thirty-eight (80%) of non-CLABSI reports included a chronology of events. Twelve (25%) non-CLABSI reports included a thorough event description, providing the clinical context of the event. Of the 446 CLABSI-related reports submitted, 11 (2%) were substantially complete. Two (0.4%) reports included an event description, and 7 (1%) included patient comorbidities. Eighty-five percent (85%) of CLABSI-related adverse event reports were submitted by one facility reflecting a significant disparity in reporting by medical facilities.

Substantial completion of the non-CLABSI reports reflects a level of buy-in to the reporting program that is encouraging. The minimal information supplied in the CLABSI-related reports represents an area for further inquiry. An advisory group will be convened to address all recommendations, with an emphasis on CLABSI reporting. District healthcare providers are amenable to the formation of such an advisory group to analyze and suggest improvements to CLABSI-related adverse event reporting. Substantial completion of all event reports submitted would supply the clinical context of the event, allowing a more meaningful analysis. Specific elements to include in an event description are the diagnosis, relevant comorbidities, a chronology, and patient outcome. However, a thorough event description is only one element of the reporting program. The opportunity to share lessons learned through the inclusion of a meaningful CAP is the foundation of a robust patient safety improvement program. Patient-specific CAPs were provided in 24 (4%) of the 524 reports included in the analysis of submitted reports. The inclusion of individualized CAPs is a significant area for improvement in the reporting program and would be a valuable source of risk reduction strategies.

Technical Credits

This report was prepared for the Department of Health by ECRI Institute. ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures, and drug technology.